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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**
Boris P. Kovatchev et al.	
Serial No. 10/524,094	Appeal No.:
Filed: February 9, 2005	Examiner: L. Clow
For: Method, system, and computer program product for the processing of self-monitoring blood glucose (SMBG) data to enhance diabetic self-management	Group Art Unit: 1631
	July 6, 2010

BRIEF ON APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This is an appeal from the rejection of claims 1 – 39 and 112 - 226 of the above-identified application, which claims were rejected in the Office action dated April 6, 2010, reopening prosecution after the filing of an Appeal Brief. A Notice of Appeal is filed concurrently herewith.

REAL PARTY IN INTEREST

The real party in interest in this case is University of Virginia Patent Foundation, of Charlottesville, Virginia.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

STATUS OF THE CLAIMS

Claims 1 – 226 are pending in the application and stand finally rejected. Claims 40 – 111 stand withdrawn from further consideration on the merits. Claims 1, 19, 37, 38, 135, 155, 175, 195, 215 and 221 constitute the independent claims on appeal. This appeal is directed to claims 1 – 39 and 112 – 226.

STATUS OF AMENDMENTS

The Advisory action dated October 15, 2009 indicated that the amendment after final rejection filed in this application on September 9, 2009 would be entered, and the Advisory action dated September 18, 2009 indicated that Appellant's response had overcome the rejection based on the first paragraph of 35 U.S.C. § 112. Moreover, reopening of prosecution by the new non-final Office action dated April 6, 2010, after appeal, has the effect of causing all prior-filed amendments to be entered.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates generally to the field of medical diagnostics, and in particular to a computer-based system and method for management of diabetes in individuals.

Specifically, the invention relates to glycemic control of individuals with diabetes, by determining glycosylated hemoglobin (HbA_{1c} and HbA_1) levels and predicting risk of incurring hypoglycemia, from collected self-monitored blood glucose data (SMBG). Severe hypoglycemia is a possible adverse effect of intensive insulin therapy. It is well-known that glycosylated hemoglobin is a marker for the glycemic control of individuals with either Type I or Type II diabetes. It is also known that HbA_{1c} reflects the average BG levels of a patient over the previous two months. Contemporary home blood glucose (BG) monitors allow the frequent measurement of blood glucose levels, but there are no reliable methods for evaluating HbA_{1c} and recognizing imminent risk of hypoglycemia based on SMBG readings. The present invention provides such a method, for evaluating HbA_{1c} and the risk of hypoglycemia from SMBG data collected from an individual, such as through use of a home BG monitor.

Claim 1

In accordance with the invention as set forth in claim 1, a method is provided for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35):

validating the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29);

electronically transforming the estimate into a visual depiction (page 19, lines 12 – 15; page 89, line 5 to page 91, line 5); and

outputting the visual depiction of the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 19

In accordance with the invention as set forth in claim 19, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35),

validate the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 37

In accordance with the invention as set forth in claim 37, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient (page 20, lines 17 – 28);

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35);

validate the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 38

In accordance with the invention as set forth in claim 38, a computer program product is provided comprising a tangible computer readable medium having computer program logic for enabling at least one processor in a computer system to evaluate the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration (Fig. 6, memory 608, 610, 618, 622), said computer program logic comprising:

pre-processing of the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data (page 12, lines 17 – 21; page 76, lines 9 - 35), and

validation of the estimate via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29); and

outputting the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 135

In accordance with the invention as set forth in claim 135, a method is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validation of a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29),

estimating HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35),

electronically transforming the estimate into a visual depiction (page 19, lines 12 – 15; page 89, line 5 to page 91, line 5), and

outputting the visual depiction of the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 155

In accordance with the invention as set forth in claim 155, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validate a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29), and

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 175

In accordance with the invention as set forth in claim 175, a system is provided for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient (page 20, lines 17 – 28);

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

validate a sample of the acquired BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29);

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the HbA_{1c} estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 195

In accordance with the invention as set forth in claim 195, a method is provided for evaluating the HbA_{1c} of a patient without the need for prior HbA1c information based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validation of a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29),

estimating HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35);

electronically transforming the estimate into a visual depiction (page 19, lines 12 – 15; page 89, line 5 to page 91, line 5); and

outputting the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 215

In accordance with the invention as set forth in claim 215, a system is provided for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7),

validate a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29), and

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

Claim 221

In accordance with the invention as set forth in claim 221, a system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on

blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient (page 20, lines 17 – 28);

a database component operative to maintain a database identifying said BG data (page 22, line 27); and

a processor programmed to (page 22 , lines 16 – 19):

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data (page 11, line 20 to page 12, line 10; page 75, line 17 to page 76, line 7);

validate a sample of the collected BG data via sample selection criteria (page 13, lines 10 – 25; page 77, line 19 to page 82, line 29);

estimate HbA_{1c} from said derived BG data if the sample is valid (page 12, lines 17 – 21; page 76, lines 9 - 35); and

output the HbA_{1c} estimate to a user (page 91, lines 6 – 12, Fig. 6, display 630; Fig. 8, display 814).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

This appeal presents the following issues for review by the Board:

1) Whether the Examiner erred in rejecting claims 1 – 18, 112, 113, 135 – 154, and 195 – 214 as allegedly being directed to non-statutory subject matter under 35 U.S.C. § 101;

2) Whether the Examiner erred in rejecting claims 6, 8 – 10, 24, 26 – 28, 120, 122 – 124, 140, 142 – 144, 160, 162 – 164, 180, 182 – 184, 200, 202 – 204, 220 and 226 under the second paragraph of 35 U.S.C. § 112 as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention;

3) Whether the Examiner erred in rejecting claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 175, 179, 195, 199, 215, 219, 221 and 225 under 35 U.S.C. § 102(b) as being anticipated by Kovatchev et al., "Symmetrization of the Blood Glucose Measurement Scale and Its Applications," Diabetes Care, Vol. 20, No. 11, November 1997, pp. 1655-1658 ("Kovatchev");

4) Whether the Examiner erred in rejecting claims 1, 19, 37, 38, 135, 155, 175, 195, 215 and 221 under 35 U.S.C. § 102(e) as being anticipated by Heinonen et al. U.S. Patent No. 6,421,633 ("Heinonen").

ARGUMENT

The Rejection of Claims 1 – 18, 112, 113, 135 – 154, and 195 - 214 Is Improper

Claims 1 – 18, 112, 113, 135 – 154, and 195 – 214 have been deemed non-statutory because "the method claims are not so tied to another statutory class of invention because the method steps that are critical to the invention are not 'tied to any **particular apparatus** or **machine**' and they do not provides *(sic)* a transformation to a different state or thing and therefore do not meet the machine-or-transformation test as set forth in *In re Bilski* 545 F.3d 943, 88 USPQ2d 1385 (Federal Circuit, 2008) *(sic)*." Office action at 4 (emphasis in original). This conclusion is erroneous.

The United States Supreme Court has recently ruled that the "machine-or-transformation test" is not the exclusive test for determining whether claims are directed to statutory subject matter. Bilski v. Kappos, Slip Opinion, June 28, 2010, p. 7 ("The Court is unaware of any "'ordinary, contemporary, common meaning,'" *Diehr, supra*, at 182, of the definitional terms "process, art or method" that would require these terms to be tied to a machine or to transform an article.") The Court explained that "[i]n searching for a limiting principle, this Court's precedents on the unpatentability of abstract ideas provide useful tools. Slip Opinion at 12.

The appealed claims in this case are not directed to abstract intellectual concepts such as converting binary-coded-decimal numbers to binary numbers, as in Gottschalk v. Benson, 409 U.S. 63,175 USPQ 673 (1972). Neither are the claims directed to mental processes, such as managing the consumption risk costs of a

commodity, as in In re Bilski, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008). Neither are the claims directed to phenomena of nature, such as the properties of inhibition or of non-inhibition in Rhizobia bacteria, as in Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

To the contrary, the appealed claims to a specific method of estimating the glycosylated hemoglobin of a patient and communicating the estimate to a user, are directed to a method that pertains to analysis of quantitative physical characteristics of a physical patient, and that has practical application in the prevention or treatment of an adverse physical condition of a patient. Thus, under Bilski v. Kappos, the claims represent statutory subject matter.

However, the claims represent statutory subject matter even under the Bilski test. In particular, because the claimed method is applied to data representative of the physical element of a patient's blood composition, it meets the "transformation" test because it converts SMBG data representative of blood glucose, to an estimate of HbA_{1c} data representative of glycosylated hemoglobin.

The Office action alleges that "[t]he claims do not, as Applicant seems to indicate, meet the transformation test by merely taking *data representative* of the physical element of a patient's blood and converting it to another type of data (SMBG data) because no transformation takes place." Office action at 5. The Office action is incorrect; the claims meet the test for "transformation" enunciated in Bilski.

In Bilski, the Court explained that the "transformation" part of the test is met where the data represents physical and tangible objects, and electronic transformation of data into a visual depiction is set forth:

> In contrast, we held one of Abele's dependent claims to be drawn to patent-eligible subject matter where it specified that "said data is X-ray attenuation data produced in a two dimensional field by a computed tomography scanner." Abele, 684 F.2d at 908-09. This data clearly represented physical and tangible objects, namely the structure of bones, organs, and other body tissues. Thus, the transformation of that raw data into a particular visual depiction of a physical object on a display was sufficient to render that more narrowly-claimed process patent-eligible.
>
> We further note for clarity that the electronic transformation of the data itself into a visual depiction in Abele was sufficient; the claim was not required to involve any transformation of the underlying physical object that the data represented. We believe this is faithful to the concern the Supreme Court articulated as the basis for the machine-or-transformation test, namely the prevention of pre-emption of fundamental principles. So long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle.

88 USPQ2d at 1397.

Here, the claims all set forth electronic transformation of the estimate data into a visual depiction that is presented to a user, and thus, satisfies the "transformation" test as enunciated in In re Bilski.

The Office action states further, that if the claims recited a step of "collecting a blood sample from a patient," and then "process the blood to calculate BG data," then the claim would meet the "transformation" arm of the test. Office action at 5-6. This

statement in the Office action provides additional evidence that the claims as currently pending are not directed to abstract ideas and thus represent statutory subject matter. In particular, the claims recite a "method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration." Thus, the method already requires that blood glucose data be collected from a patient. If no blood glucose data were collected from a patient, then the method could not be performed, because as claimed, it depends upon possession of such data.

In view of the foregoing, the rejection of claims as being directed to non-statutory subject matter is in error, and must be reversed.

The Rejection of Claims 6, 8 – 10, 24, 26 – 28, 120, 122 – 124, 140, 142 – 144, 160, 162 – 164, 180, 182 – 184, 200, 202 – 204, 220 and 226 as Being Indefinite Is Improper

The rejection of claims 6, 8 – 10, 24, 26 – 28, 120, 122 – 124, 140, 142 – 144, 160, 162 – 164, 180, 182 – 184, 200, 202 – 204, 220 and 226 under the second paragraph of 35 U.S.C. § 112 as being indefinite, is improper and should be reversed. The rejection newly alleges that the language "using a predetermined mathematical formula defined as" is indefinite because "each of the recited claims fails to recite any such mathematical formula." Office action at 6. This assertion is erroneous.

In particular, the Office action erroneously states that the claims define merely certain criteria without any association to an actual formula. To the contrary, actual mathematical formulae are in fact set forth in the claims under rejection. For example, claim 6 requires that Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) be computed using a predetermined mathematical formula defined as RLO1 = average of RiskLO per patient, and RHI1 = average of RiskHI per patient. These are actual mathematical formulae. The remainder of claim 6 goes on to define RiskLO and RiskHI, for example: RiskLO=Risk1 if (BG is less than about 112.5), otherwise RiskLO=0; Risk1 = $22.765(\text{Scale})^2$; and Scale=$[\ln(\text{BG})]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl.

Thus, claim 6 (and by analogy the remainder of the claims rejected on this ground) sets forth the full mathematical formula to compute RLO1 and RHI1, as stated. There is nothing indefinite about the various mathematical formulae or equations as set forth in the rejected claims, whether considered in the context of the claims alone, or when considered with reference to the specification as claim language must be considered when determining the issue of definiteness under 35 U.S.C. 112 second paragraph. This ground of rejection is thus in error and must be reversed.

The Rejection of Claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 175, 179, 195, 199, 215, 219, 221 and 225 under 35 U.S.C. § 102(b) as Being Anticipated by Kovatchev Is In Error And Should Be Reversed

The rejected claims require pre-processing collected BG data to convert the collected BG data into derived BG data derived from said collected BG data, estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data, validating the estimate via sample selection criteria; electronically transforming the estimate into a visual depiction; and outputting the visual depiction of the estimate to a user.

Kovatchev (which not only was cited in an Information Disclosure Statement filed July 19, 2006, but is discussed in detail in the present specification at pages 4 – 6) is directed to symmetrization of the blood glucose measurement scale. Kovatchev explains that in the standard blood glucose scale, hypoglycemia and hyperglycemia have very different ranges, and euglycemia is not central in the entire blood glucose range. Consequently, the scale is not symmetric and its clinical center (blood glucose 6-7 mmol/l) is distant from its numerical center (blood glucose 17 mmol/l). Kovatchev thus proposes a logarithmic data transformation that matches the clinical and numerical center of the blood glucose scale, thus making the transformed data symmetric.

Kovatchev does not disclose estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data as required by the claims. Kovatchev states at page 1655, column three, that the logarithmic-type transformation of blood

glucose scale data serves as a basis for defining the blood glucose risk indexes, which, given multiple SMBG readings, predict the subjects' glycosylated hemoglobin levels and the likelihood for severe hypoglycemia. Kovatchev goes on to explain that the high blood glucose index was positively correlated with subjects' glycosylated hemoglobin values (page 1657, col. 1). It is here noted that the low and high blood glucose indexes as set forth in the claims on appeal relate to the recited pre-processing of the collected blood glucose data and do not correspond to the application of at least one predetermined formula to derived BG data to estimate HbA_{1c} as claimed.

Prediction of a subject's glycosylated hemoglobin level from blood glucose risk indexes, as in noting a positive correlation, does not teach and does not correspond to estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data, validating the estimate via sample selection criteria; electronically transforming the estimate into a visual depiction; and outputting the visual depiction of the estimate to a user, as required by the claims. The Office action has not even alleged that such corresponds to the specific claim limitations, and consequently the Office action fails to state a *prima facie* case. This ground of rejection must be reversed.

The Rejection of Claims 1, 19, 37, 38, 135, 155, 175, 195, 215 and 221 Under 35 U.S.C. § 102(e) as Being Anticipated By Heinonen Is In Error and Must Be Reversed

Heinonen discloses a method of predicting HbA1c by developing a model that correlates measured blood glucose levels with correspondingly measured HbA1c levels. See Fig. 1. When subsequent blood glucose measurements are taken, they are applied to the model to obtain a corresponding predicted HbA1c level. In other words, Heinonen discloses the generation of a sort of HbA1c "look-up table" where a set of blood glucose measurements is associated with a corresponding set of HbA1c measurements taken at the same time as the blood glucose measurements. See col. 4, line 66 – col. 5, line 9. The "look-up table" is periodically updated as new HbA1c measurements are made. Col. 6, lines 17 – 21.

Heinonen does not pre-process collected BG data to convert the collected BG data into derived BG data derived from the collected BG data; estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data; validate the estimate via sample selection criteria; electronically transform the estimate into a visual depiction; or output the visual depiction of the estimate to a user as required by the claims on appeal.

The Office action further fails to set forth a *prima facie* case of anticipation. The Office action alleges only that Heinonen "teach a method and system whereby levels of HbA1c are predicted using a mathematical model which is derived to predict the

behavior of Hb1c relative to blood glucose (abstract, column 2, lines 20 -53), therefore meeting the limitations of converting BG data and estimating HbA1c and providing an output of the data (Figure 6)." The claims on appeal, however, do not claim predicting levels of HbA1c using a mathematical model which is derived to predict the behavior of Hb1c relative to blood glucose. The rejection is improper and must be reversed.

CONCLUSION

In view of the foregoing, claims 1 – 39 and 112 – 226 are submitted to be directed to a new and unobvious method, system and computer program product for evaluation of the glycosylated hemoglobin of a patient, which is not taught by the prior art and which fully comply with the statutory category of invention and definiteness requirements of the patent laws. The Honorable Board is respectfully requested to reverse all grounds of rejection and to direct the passage of this application to issue.

Please charge any fee or credit any overpayment pursuant to 37 CFR 1.16 or 1.17 to Novak Druce Deposit Account No. 14-1437.

Respectfully submitted,

NOVAK, DRUCE, DELUCA + QUIGG LLP

Vincent M DeLuca

By _____

Vincent M. DeLuca
Attorney for Appellants
Registration No. 32,408

300 New Jersey Avenue, N.W.
Fifth Floor
Washington, D.C. 20001
Telephone: (202)659-0100

APPENDIX OF CLAIMS ON APPEAL

1. (previously presented) A method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

   pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

   estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data,

   validating the estimate via sample selection criteria;

   electronically transforming the estimate into a visual depiction; and

   outputting the visual depiction of the estimate to a user.

2. (original) The method of claim 1, wherein said first predetermined duration is about 60 days.

3. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 75 days.

4. (original) The method of claim 1, wherein said first predetermined duration ranges from about 45 days to about 90 days.

5. (previously presented) The method of claim 1, wherein the pre-processing of the data comprises:

   conversion of plasma data to whole blood BG mg/dl;

   conversion of BG measured in mg/dl to units of mmol/l; and

   computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

6. (previously presented) The method of claim 1, wherein the preprocessing of the data comprises :

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

7. (original) The method of claim 6, wherein the N06, N12, N24 are percentage of

SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

8. (original) The method of claim 6, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

9. (original) The method of claim 8, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

10. (original) The method of claim 9, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

11. (previously presented) The method of claim 10 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration,

said estimating HbA_{1c} comprising:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 6.

RLO1 is the Low BG Index of claim 6.

RHI1 is the High BG Index of claim 6; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA1c reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 6; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 6.

12. (original) The method of claim 11, wherein said second predetermined duration is about three months.

13. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

14. (original) The method of claim 11, wherein said second predetermined duration ranges from about 2.5 months to six months.

15. (previously presented) The method of claim 11, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 6.

16. (original) The method of claim 15, wherein said third predetermined duration is at least 35 days.

17. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about 40 days.

18. (original) The method of claim 15, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

19. (currently amended) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data,

validate the estimate via sample selection criteria; and

output the estimate to a user.

20. (original) The system of claim 19, wherein said first predetermined duration is about 60 days.

21. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 75 days.

22. (original) The system of claim 19, wherein said first predetermined duration ranges from about 45 days to about 90 days.

23. (previously presented) The system of claim 19, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

24. (previously presented) The system of claim 19, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

25. (original) The system of claim 24, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

26. (original) The system of claim 24, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

27. (original) The system of claim 26, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

28. (original) The system of claim 27, comprising providing further correction of the

estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

29. (previously presented) The system of claim 28 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, wherein said estimating HbA_{1c} comprises :

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 24,

RLO1 is the Low BG Index of claim 24,

RHI1 is the High BG Index of claim 24; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 24; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 24.

30. (original) The system of claim 29, wherein said second predetermined duration is about three months.

31. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

32. (original) The system of claim 29, wherein said second predetermined duration ranges from about 2.5 months to six months.

33. (previously presented) The system of claim 29, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 24,

RHI1 is the High BG Index of claim 24; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 24.

34. (original) The system of claim 33, wherein said third predetermined duration is at least 35 days.

35. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about 40 days.

36. (original) The system of claim 33, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

37. (previously presented) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data;

estimate HbA_{1c} by applying at least one predetermined formula to said derived BG data;

validate the estimate via sample selection criteria; and

output the estimate to a user.

38. (previously presented) A computer program product comprising a tangible computer readable medium having computer program logic for enabling at least one processor in a computer system to evaluate the HbA_{1c} of a patient based on

blood glucose (BG) data collected over a first predetermined duration, said computer program logic comprising:

pre-processing of the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data, and

validation of the estimate via sample selection criteria; and

outputting the estimate to a user.

39. (original) The computer program product of claim 38, wherein said computer program logic further comprises the steps of claim 11.

112. (previously presented) The method of claim 11, wherein the validation of the HbA1c estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 6

RHI1 is the High BG Index of claim 6; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 6.

113. (original) The method of claim 112, wherein said third predetermined duration is at least about 35 days.

114. (previously presented) The system of claim 29, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 24

RHI1 is the High BG Index of claim 24; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 24.

115. (original) The system of claim 114, wherein said third predetermined duration is at least about 35 days.

116. (previously presented) The system of claim 37, wherein said first predetermined duration is about 60 days.

117. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 75 days.

118. (previously presented) The system of claim 37, wherein said first predetermined duration ranges from about 45 days to about 90 days.

119. (previously presented) The system of claim 37, wherein the pre-processing of the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

120. (previously presented) The system of claim 37, wherein the preprocessing of the data comprises:

conversion of plasma data to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

121. (previously presented) The system of claim 120, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

122. (previously presented) The system of claim 120, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

123. (previously presented) The system of claim 122, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

124. (previously presented) The system of claim 123, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

125. (previously presented) The system of claim 124 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

said estimating HbA_{1c} using said at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 120,

RLO1 is the Low BG Index of claim 120,

RHI1 is the High BG Index of claim 120; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 120; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 120.

126. (previously presented) The system of claim 125, wherein said second predetermined duration is about three months.

127. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

128. (previously presented) The system of claim 125, wherein said second predetermined duration ranges from about 2.5 months to six months.

129. (previously presented) The system of claim 125, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 120,

RHI1 is the High BG Index of claim 120; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 120.

130. (previously presented) The system of claim 129, wherein said third predetermined duration is at least 35 days.

131. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about 40 days.

132. (previously presented) The system of claim 129, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

133. (previously presented) The system of claim 125, wherein the validation of the HbA_{1c} estimate using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 120

RHI1 is the High BG Index of claim 120; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 120.

134. (previously presented) The system of claim 133, wherein said third predetermined duration is at least about 35 days.

135. (previously presented) A method for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validation of a sample of the collected BG data via sample selection criteria,

estimating HbA_{1c} from said derived BG data if the sample is valid,

electronically transforming the estimate into a visual depiction, and

outputting the visual depiction of the estimate to a user.

136. (previously presented) The method of claim 135, wherein said first predetermined duration is about 60 days.

137. (previously presented) The method of claim 135, wherein said first predetermined duration ranges from about 45 days to about 75 days.

138. (previously presented) The method of claim 135, wherein said first predetermined duration ranges from about 45 days to about 90 days.

139. (previously presented) The method of claim 135, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

140. (previously presented) The method of claim 135, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

141. (previously presented) The method of claim 140, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

142. (previously presented) The method of claim 140, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

143. (previously presented) The method of claim 142, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

144. (previously presented) The method of claim 143, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

145. (previously presented) The method of claim 144 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 140.

RLO1 is the Low BG Index of claim 140.

RHI1 is the High BG Index of claim 140; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second

predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 140; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 140.

146. (previously presented) The method of claim 145, wherein said second predetermined duration is about three months.

147. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

148. (previously presented) The method of claim 145, wherein said second predetermined duration ranges from about 2.5 months to six months.

149. (previously presented) The method of claim 145, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 140

RHI1 is the High BG Index of claim 140; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 140.

150. (previously presented) The method of claim 149, wherein said third predetermined duration is at least 35 days.

151. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about 40 days.

152. (previously presented) The method of claim 149, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

153. (previously presented) The method of claim 145, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 149

RHI1 is the High BG Index of claim 140; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 140.

154. (previously presented) The method of claim 153, wherein said third predetermined duration is at least about 35 days.

155. (previously presented) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validate a sample of the collected BG data via sample selection criteria, and

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the estimate to a user.

156. (previously presented) The system of claim 155, wherein said first predetermined duration is about 60 days.

157. (previously presented) The system of claim 155, wherein said first predetermined duration ranges from about 45 days to about 75 days.

158. (previously presented) The system of claim 155, wherein said first predetermined duration ranges from about 45 days to about 90 days.

159. (previously presented) The system of claim 155, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

160. (previously presented) The system of claim 155, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

161. (previously presented) The system of claim 160, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

162. (previously presented) The system of claim 160, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

163. (previously presented) The system of claim 162, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

164. (previously presented) The system of claim 163, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

165. (previously presented) The system of claim 164 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 160,

RLO1 is the Low BG Index of claim 160,

RHI1 is the High BG Index of claim 160; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 160; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 160.

166. (previously presented) The system of claim 165, wherein said second predetermined duration is about three months.

167. (previously presented) The system of claim 165, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

168. (previously presented) The system of claim 165, wherein said second predetermined duration ranges from about 2.5 months to six months.

169. (previously presented) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 160,

RHI1 is the High BG Index of claim 160; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 160.

170. (previously presented) The system of claim 169, wherein said third predetermined duration is at least 35 days.

171. (previously presented) The system of claim 169, wherein said third predetermined duration ranges from about 35 days to about 40 days.

172. (previously presented) The system of claim 169, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

173. (previously presented) The system of claim 165, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 160

RHI1 is the High BG Index of claim 160; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 160.

174. (previously presented) The system of claim 173, wherein said third predetermined duration is at least about 35 days.

175. (previously presented) A system for evaluating the HbA_{1c} of a patient based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the acquired BG data to convert the acquired BG data into derived BG data derived from said acquired BG data;

validate a sample of the acquired BG data via sample selection criteria;

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the HbA_{1c} estimate to a user.

176. (previously presented) The system of claim 175, wherein said first predetermined duration is about 60 days.

177. (previously presented) The system of claim 175, wherein said first predetermined duration ranges from about 45 days to about 75 days.

178. (previously presented) The system of claim 175, wherein said first predetermined duration ranges from about 45 days to about 90 days.

179. (previously presented) The system of claim 175, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

180. (previously presented) The system of claim 175, wherein the pre-processing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

$Scale=[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

$Risk1 = 22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

181. (previously presented) The system of claim 180, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

182. (previously presented) The system of claim 180, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

183. (previously presented) The system of claim 182, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

184. (previously presented) The system of claim 183, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

185. (previously presented) The system of claim 184 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said system comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 180,

RLO1 is the Low BG Index of claim 180,

RHI1 is the High BG Index of claim 180; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second

predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 180; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 180.

186. (previously presented) The system of claim 185, wherein said second predetermined duration is about three months.

187. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

188. (previously presented) The system of claim 185, wherein said second predetermined duration ranges from about 2.5 months to six months.

189. (previously presented) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 180,

RHI1 is the High BG Index of claim 180; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 180.

190. (previously presented) The system of claim 189, wherein said third predetermined duration is at least 35 days.

191. (previously presented) The system of claim 189, wherein said third predetermined duration ranges from about 35 days to about 40 days.

192. (previously presented) The system of claim 189, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

193. (previously presented) The system of claim 185, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 180

RHI1 is the High BG Index of claim 180; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 180.

194. (previously presented) The system of claim 193, wherein said third predetermined duration is at least about 35 days.

195. (previously presented) A method for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validation of a sample of the collected BG data via sample selection criteria,

estimating HbA_{1c} from said derived BG data if the sample is valid;

electronically transforming the estimate into a visual depiction; and

outputting the estimate to a user.

196. (previously presented) The method of claim 195, wherein said first predetermined duration is about 60 days.

197. (previously presented) The method of claim 195, wherein said first predetermined duration ranges from about 45 days to about 75 days.

198. (previously presented) The method of claim 195, wherein said first predetermined duration ranges from about 45 days to about 90 days.

199. (previously presented) The method of claim 195, wherein the preprocessing of

the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

200. (previously presented) The method of claim 195, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l) via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

201. (previously presented) The method of claim 200, wherein the N06, N12, N24 are percentage of SMBG readings in time intervals of about 0-6:59 hour time period; about 7-12:59 hour time period, and about 18-23:59 hour time period, respectively.

202. (previously presented) The method of claim 200, comprising assigning a group depending on the patient's computed High BG Index using a predetermined mathematical formula defined as:

if (RHI1 is ≤about 5.25 or if RHI1 is ≥about 16) then the assigned group= 0,

if (RHI1 is > about 5.25 and if RHI1 is < about 7.0) then the assigned group=1,

if (RHI1 is ≥about 7.0 and if RHI1 is < about 8.5) then the assign group=2, and

if (RHI1 is ≥about 8.5 and if RHI1 is <about 16) then the assigned group=3.

203. (previously presented) The method of claim 202, comprising providing estimates using a predetermined mathematical formula defined as:

E0 = 0.55555*BGMM1+2.95,

E1 = 0.50567*BGMM1+0.074*L06+2.69,

E2 = 0.55555*BGMM1-0.074*L06+2.96,

E3 = 0.44000*BGMM1+0.035*L06+3.65; and

if (Group = 1) then EST2=E1, or if (Group = 2) then EST2=E2, or if (Group = 3) then EST2=E3, otherwise EST2=E0.

204. (previously presented) The method of claim 203, comprising providing further correction of the estimates using a predetermined mathematical formula defined as:

if (missing(L06)) EST2=E0,

if (RLO1 is ≤about 0.5 and RHI1 is le about 2.0) then EST2=E0-0.25,

if (RLO1 is ≤about 2.5 and RHI1 is > about 26) then EST2=E0-1.5*RLO1, and

if ((RLO1/RHI1) is ≤about 0.25 and L06 is > about 1.3) then EST2=EST2-0.08.

205. (previously presented) The method of claim 204 for estimating the HbA_{1c} of a patient based on BG data collected over the first predetermined duration, said method comprising:

estimating HbA_{1c} using at least one of four predetermined mathematical formulas defined as:

a) HbA_{1c} = the EST2 defined by claim 8 or as corrected by claim 10 or

b) HbA_{1c} = 0.809098*BGMM1 + 0.064540*RLO1 - 0.151673*RHI1 + 1.873325, wherein

BGMM1 is the average BG (mmol/l) of claim 200,

RLO1 is the Low BG Index of claim 200,

RHI1 is the High BG Index of claim 200; or

c) HbA_{1c} = 0.682742*HBA0 + 0.054377*RHI1 + 1.553277, wherein

HBA0 is a previous reference HbA_{1c} reading taken about a second predetermined period prior to the estimate, wherein

RHI1 = is the High BG Index of claim 200; or

d) HbA_{1c} = 0.41046*BGMM + 4.0775

wherein BGMM1 is the average BG (mmol/l) of claim 200.

206. (previously presented) The method of claim 205, wherein said second predetermined duration is about three months.

207. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to about 3.5 months.

208. (previously presented) The method of claim 205, wherein said second predetermined duration ranges from about 2.5 months to six months.

209. (previously presented) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5 to about 2.5 tests per day;

b) an alternative test frequency criterion only if the predetermined duration sample contains at least a third predetermined sample period with readings with an average frequency of about 1.8 readings/day;

c) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 200

RHI1 is the High BG Index of claim 200; or

d) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%).

wherein

N06 is the percentage of readings during the night of claim 200.

210. (previously presented) The method of claim 209, wherein said third predetermined duration is at least 35 days.

211. (previously presented) The method of claim 209, wherein said third predetermined duration ranges from about 35 days to about 40 days.

212. (previously presented) The method of claim 209, wherein said third predetermined duration ranges from about 35 days to about as long as the first predetermined duration.

213. (previously presented) The method of claim 205, wherein the validation of the sample using sample selection criteria of HbA_{1c} estimate only if the first predetermined duration sample meets at least one of the following four criteria:

a) a test frequency criterion wherein if the first predetermined duration sample contains an average of at least about 1.5; and

b) a randomness of data criterion-1 wherein the HbA_{1c} estimate is validated or displayed only if the ratio (RLO1/RHI1>= about 0.005),

wherein

RLO1 is the Low BG Index of claim 149

RHI1 is the High BG Index of claim 200; or

c) a randomness of data criterion-2 wherein HbA_{1c} estimate is validated or displayed only if the ratio (NO6 >= about 3%),

wherein

N06 is the percentage of readings during the night of claim 200.

214. (previously presented) The method of claim 213, wherein said third predetermined duration is at least about 35 days.

215. (previously presented) A system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

validate a sample of the collected BG data via sample selection criteria, and

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the estimate to a user.

216. (previously presented) The system of claim 215, wherein said first predetermined duration is about 60 days.

217. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 75 days.

218. (previously presented) The system of claim 215, wherein said first predetermined duration ranges from about 45 days to about 90 days.

219. (previously presented) The system of claim 215, wherein the preprocessing of the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

220. (previously presented) The system of claim 215, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

221. (previously presented) A system for evaluating the HbA_{1c} of a patient without the need for prior HbA_{1c} information based on blood glucose (BG) data collected over a first predetermined duration, said system comprising:

a BG acquisition mechanism, said acquisition mechanism configured to acquire BG data from the patient;

a database component operative to maintain a database identifying said BG data; and

a processor programmed to:

pre-process the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data;

validate a sample of the collected BG data via sample selection criteria;

estimate HbA_{1c} from said derived BG data if the sample is valid; and

output the HbA_{1c} estimate to a user.

222. (previously presented) The system of claim 221, wherein said first predetermined duration is about 60 days.

223. (previously presented) The system of claim 221, wherein said first predetermined duration ranges from about 45 days to about 75 days.

224. (previously presented) The system of claim 221, wherein said first predetermined duration ranges from about 45 days to about 90 days.

225. (previously presented) The system of claim 221, wherein the preprocessing of the data comprises:

conversion of plasma data to whole blood BG mg/dl;

conversion of BG measured in mg/dl to units of mmol/l; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1).

226. (previously presented) The system of claim 221, wherein the preprocessing of the data is defined as:

conversion of plasma to whole blood BG mg/dl via BG=PLASBG (mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via BGMM=BG/18; and

computing Low Blood Glucose Index (RLO1) and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as:

Scale=$[\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of mg/dl,

Risk1 = $22.765(Scale)^2$, wherein

RiskLO=Risk1 if (BG is less than about 112.5) and therefore risk of LBGI exists, otherwise RiskLO=0, and

RiskHI=Risk1 if (BG is greater than about 112.5) and therefore risk of HBGI exists, otherwise RiskHI=0,

BGMM1 = average of BGMM per patient,

RLO1 = average of RiskLO per patient,

RHI1 = average of RiskHI per patient,

L06 = average of RiskLO computed only for readings during the night, otherwise missing if there are no readings at night,

N06, N12, N24 are percentage of SMBG readings in time intervals,

NC1 = total number of SMBG readings in the first predetermined duration; and

NDAYS = number of days with SMBG readings in the first predetermined duration.

EVIDENCE APPENDIX

None.

RELATED APPEALS APPENDIX

None.